UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/848,827	05/19/2004	Phillip A. Patten	0269us410	5777

30560 7590 12/29/2006

MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
REDWOOD CITY, CA 94063

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/848,827	PATTEN ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-22,32 and 37-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-22,32 and 37-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *5/19/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6, 10/27, 11/8 & 11/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, drawn to claims 1-22 and 32 in the reply filed on 10/16/06 is acknowledged. Applicant has also elected SEQ ID NO: 12 for examination. Applicant further states that the non-polypeptide moiety covalently attached to the polypeptide is assumed to be a polymer rather than glycol and elects that. The Office accepts that assumption. Claims 2-4, 23-31 and 33-36 have been cancelled. Claims 37-45 have been added. Claims 1, 5, 8, 10, 12-16 and 32 have been amended. Claims 19-20 are withdrawn. Therefore, claims 1, 5-22, 32 and 37-45 are pending and under consideration.

Drawings

2. The drawings filed 5/19/2004 are acknowledged.

Information Disclosure Statement

3. The IDS submitted 10/06/2006, 10/27/2006, 11/08/2006 and 11/14/2006 have been considered.

Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-22, 32 and 37-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 1, 10 and 32 are rejected as vague and indefinite for reciting the term "an antiviral activity". This implies that there are multiple antiviral activities. However, the

specification on page 173 discloses a single antiviral activity. Therefore the metes and bounds of these claims are unclear because what additional activities are encompassed by the claims cannot be determined. To obviate the rejection it is suggested the Applicant rewrite the claim to include "the antiviral activity". Claims 5-9, 11-22 and 37-45 are rejected insofar as they are dependent on the rejected claims 1, 10 and 32.

4b. Claim 8 is rejected as vague and indefinite for reciting the term "an interferon-alpha antiproliferative activity". This implies that there are multiple antiproliferative activities. However, the specification on page 175 discloses a single antiproliferative activity. Therefore the metes and bounds of these claims are unclear because what additional activities are encompassed by the claims cannot be determined. To obviate the rejection it is suggested the Applicant rewrite the claim to include "the antiproliferative activity". Claim 9 is rejected insofar as they are dependent on the rejected claim 8.

Claim Rejections - 35 USC § 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1, 6-22, 32 and 37-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The claims are drawn to isolated or recombinant interferon-alpha polypeptide variants and conjugates with up to 16 amino acid residue changes from SEQ ID NO: 12 containing an interferon activity.

The specification discloses several potential interferon-alpha substitutions at positions including H47Q, V51T, F55S, L56V, Y58H, N72D, N95D, E133K, A140S, F154L, K160E, R161S, R164S of SEQ ID NO: 12. Combinations of these changes also have antiviral and/or antiproliferative activities (see Table 7 on page 174 and Table 8 on pages 176-177). This meets the written description provisions of 35 USC 112, first paragraph. However, the specification does not disclose or teach all possible variants (with up to 16 amino acid residue changes) of interferon-alpha of SEQ ID NO: 12, wherein the variants have antiviral activity. Applicants have claimed a genus of polypeptides that have no common function. Interferon-alpha has antiviral effects (page 173), T_H1 differentiation effects (page 174) and anti proliferative effects (page 175). It is not clear what combinations of substitutions will retain common functions of the wild type interferon-alpha. As seen in Table 7, samples B9x24 and 25Ep05 demonstrate that changes in few amino acids seems to affect the antiviral activity relative to huIFNα-2b almost two fold (see page 174). Furthermore, there are more than 25 amino acid changes in SEQ ID NO: 12 compared to huIFNα-2b (SEQ ID NO: 32). Therefore, it is also not clear how a further change of up to 16 amino acids to the polypeptide of SEQ

ID NO: 12 would affect the activities of interferon-alpha and conjugation of the polypeptide.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claim are a partial structure in the form of a recitation of SEQ ID number, possible amino acid changes (amino acid changes at up to 16 positions) and the desired interferon alpha activity. There is not even identification of any particular portion of the structure that must be conserved to retain specific interferon-alpha activities. The claims as written, however, encompass interferon-alpha variant sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 1, 6-22, 32 and 37-45. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of isolated interferon-alpha variant polypeptide with substitutions for example, at positions H47Q, V51T, F55S, L56V, Y58H, N72D, N95D, E133K, A140S, F154L, K160E, R161S, R164S of SEQ ID NO: 12, the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptides (with up to 16 possible amino acid changes), regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only the isolated interferon-alpha variant polypeptide with substitutions at positions H47Q, V51T, F55S, L56V, Y58H, N72D, N95D, E133K, A140S, F154L, K160E, R161S, R164S of SEQ ID NO: 12 but not the full breadth of the claims (with all 16 possible amino acids changed) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various polypeptide sequences set forth in claim 1. Claims 6-22, 32 and 37-45 are rejected insofar as they depend on rejected claim 1.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent

Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5b. Claims 1, 6-22, 32 and 37-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for interferon-alpha variant, with substitutions at positions H47Q, V51T, F55S, L56V, Y58H, N72D, N95D, E133K, A140S, F154L, K160E, R161S, R164S of SEQ ID NO: 12 which have antiviral and/or antiproliferative activities (see Table 7 on page 174 and Table 8 on pages 176-177), the disclosure does not reasonably provide enablement for all variant interferon-alpha polypeptides contemplated. In addition, it is also unclear what activity if any will be associated with the specific interferon-alpha variants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to isolated or recombinant interferon-alpha polypeptide variants and conjugates with up to 16 amino acid residue changes from SEQ ID NO: 12 containing an interferon activity.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the

invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Despite knowledge in the art for producing variants of a given polypeptide with amino acid deletions, insertions or substitutions the specification fails to provide any guidance regarding the changes/modifications contemplated and yet retain the function(s) of the interferon-alpha variants claimed. Furthermore, detailed information regarding the structural and functional requirements of the disclosed variant protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry

29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data and changes at 13 specific positions, to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein, which are tolerant to change (e.g. such as by amino acid substitutions), and the nature and extent of changes that can be made in these positions and yet retain the activity as recited in the claims. For example, as seen on Table 7, samples B9x24 and 25Ep05 illustrate how changes in a few amino acids seems to affect the antiviral activity relative to hulFNα-2b almost two fold (see page 174). It is also noted that interferon-alpha variant of SEQ ID NO: 12 differ at more than 25 positions compared to hulFNα-2b. Further changes of up to 16 more positions would change almost 25% of the full-length hulFNα-2b polypeptide. Although the specification outlines art-recognized procedures for producing and screening for active variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation obtain variants with specific interferon-alpha activities. Even if an active or binding site were identified in the specification, it may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The instant disclosure fails to disclose which if any functions of the interferon-alpha activities will remain after the mutation of the polypeptide (see

also 112/ 2nd paragraph rejections for activity limitations). Therefore, predicting which variants would retain the functions of the protein is well outside the realm of routine experimentation. Thus, undue amount of experimentation would be required to generate changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicants have not taught how one of skill in the art would use the full scope of polypeptide sequences encompassed by the invention of claims 1, 6-22, 32 and 37-45. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences. Given the breadth of claims 1, 6-22, 32 and 37-45 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior at of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claims 6-22, 32 and 37-45 are rejected insofar as they depend on rejected claim 1.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-22, 32 and 37-45 of copending Application No. 11/554, 487 ('487). Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 10 disclosed in the '487 application is sample B9x23 (see Table 7 and sequence listing page 6) only differs at a single amino acid site (H47Q) compared to SEQ ID NO: 12 of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6b. Claims 1, 6-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending Application No. 11/554, 507 ('507). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '507 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample

B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6c. Claims 1, 6-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending Application No. 11/554, 521 ('521). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '521 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6d. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending Application No. 11/554, 547 ('547). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '547 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6e. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending Application No. 11/554, 507 ('565). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '565 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6f. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6-18, 21-22 and 32 of copending Application No. 10/714, 817 ('817). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '817 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6g. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 24-35, 38-40, 44, 46, 47, 48, 64, 69 and 74 of copending Application No. 11/352, 045 ('045). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequence of SEQ ID NO: 13 of '045 application differs from SEQ ID NO: 12 at 6 amino acid positions (see Table 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6h. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 24-35, 38-40, 44, 46, 47, 48, 64, 69 and 74 of copending Application No. 11/352, 024 ('024). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequence of SEQ ID NO: 13 of '024 application differs from SEQ ID NO: 12 at 6 amino acid positions (see Table 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6i. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-7, 12 and 25 of copending Application No. 11/569, 345 ('345). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequences contemplated in claim 1 of '345 application also includes SEQ ID NO: 12 of the instant invention (see claim 1). Furthermore, sample

B9x14 (SEQ ID NO: 3) differs from SEQ ID NO: 12 at 16 amino acid positions (see page 2 of the sequence listing).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6j. Claims 1, 5-22, 32 and 37-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 24-35, 38-40, 44, 46, 47, 48, 64, 69 and 74 of copending Application No. 11/132, 722 ('722). Although the conflicting claims are not identical, they are not patentably distinct from each other because polypeptide sequence of SEQ ID NO: 13 of '722 application differs from SEQ ID NO: 12 at 6 amino acid positions (see Table 2).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

7.The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(i) Brugger et al. (WO 2004/045648 A1, PTO1449 of 10/06/2006), discloses positional isomers of PEG IFN alpha 2a),

(ii) Foser et al. (2003, PTO1449 of 10/27/2006) teaches isolation, structural characterization, and antiviral activity of positional isomers of monopegylated interferon α-2a (PEGASYS). These references do not disclose SEQ ID NO: 12.

8. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS
Art Unit 1647
December 19, 2006.

Jegatheesan Seharaseyon.
Patent Examiner